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BASF Corporation

BASF

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U.S. Environmental Protection Agency
Enforcement and Compliance Docket and Information Center
Mail Code 2201A
Attn: Docket Number EC-2000-007
1200 Pennsylvania Avenue NW
Washington, DC 20460

Dear Sir or Madam:

BASF Corporation is pleased to provide comments on the proposed rule regarding Establishment of Electronic Reporting: Electronic Records published in 66 Fed. Reg. 46162-46195 (August 31, 2001) (Proposed Rule). We also support the comments submitted by the American Chemistry Council and Society of Quality Assurance. BASF manufactures and distributes a diverse range of products, including high-value chemicals, plastics, dyestuffs, dispersions, automobile and industrial coatings, crop protection products, and fine chemicals, which are impacted in many ways by all of EPA's programs. We recognize the need for regulations and guidance around practices concerning electronic reporting and recordkeeping, however, we feel that under the circumstances, the recordkeeping portion of the proposed rule should be withdrawn at this time. The reasons for this opinion are:

A. That the Proposed Rule is not voluntary as written, but would be mandatory for any EPA regulated entity that currently generates an e-record.
B. The number of entities affected and the costs to develop compliance procedures are grossly underestimated. Estimates run as high as 1.2 million entities affected immediately with cost effects to the economy ranging from 48 billion to 1.8 trillion dollars, vs. the 400 "average" number of facilities per year and $40,000 per facility cost listed in the Proposed Rule. BASF has over 50 facilities, each with multiple computer system platforms used for compliance monitoring and recordkeeping that will be impacted by the Proposed Rule.
C. There is no differentiation between types of electronic records, but rather a "one size fits all" approach for all e-record criteria. This approach gives no consideration to the vastly different types of systems currently in use to adhere to CFR Title 40.
D. The rapid changes in technology will require a tremendous burden on meeting regulatory requirements for maintaining electronic records for a long record retention period which, in some cases, can last decades or be 'indefinite'.
E. Often original data is generated by a contract laboratory and tools are not available by the regulated entity to access the raw data or to archive it.

We also have concerns on reporting and the CDX technology that will be needed for various State and EPA programs, and that the cumbersome process outlined in the rule will be an unreasonable burden on industry.

Non-Voluntary Aspect of Rule

Throughout the Proposed Rule, EPA asserts that it is voluntary. Entities may choose to report and keep electronic records if they wish, provided that the Agency publishes a notice in the Federal Register each time a program is ready to accept and allow electronic reporting and recordkeeping. The Proposed Rule, however, overlooks the fact that many entities have been collecting electronic records for years, and, in some cases, are now already reporting electronically to the EPA or state agency. (For example, 40 CFR 75.73(e)(1) & (f)(1)). Within FIFRA, raw data is collected by electronic instruments such as gas chromatographs (GCs), mass spectrometers (MS), etc. All of these instruments collect the data into electronic files, which is then reviewed and printed out. The printout is considered the official raw data, and is archived with the study. The instruments all have validation to ensure they are operating properly, but the electronic record is stored for only a short time period. The Proposed Rule would drastically change this process, discounting the printout and forcing the facility to maintain the electronic file instead, often for an extremely long time period. It is unreasonable to think that the rule could be voluntary under these circumstances, as no entity could actually change their current processes from electronic back to paper, based on the definitions given in the rule.

Additionally, environmental monitoring labs are contracted extensively by the regulated industry for compliance data. These laboratories extensively use electronic data collection on their instruments. Besides the complex instruments like GCs and GC/MS, even balances can be automated to save time in weighing samples and insure accuracy. Most of the time, the regulated industry receives a paper copy of the final report and does not see the raw data and metadata (calibrations, subsample weights, etc.) involved. Usually, we do not have the software it takes to look at the data and would have no way to archive the raw data from these labs so that they may be retrieved.

In addition, what would it mean for regulated entities that are currently collecting and submitting e-records, if the Proposed Rule becomes final and the EPA program has not yet published that it is allowable for them to do so? Will they be out of compliance? The Agency has stated that this was not the intent of the proposed rule, however, it is the perception based on the descriptions listed in the preamble. The recordkeeping portion of the Proposed Rule should not go forward until these issues are resolved.

Number of Sites Affected

There are over 50 BASF sites affected and additional contract facilities that are currently used. Each site has multiple systems that might fall under the rule and not just one computer per site, which EPA estimates.

EPA maintains that the costs for implementing the Proposed Rule would be a mere $40,000 the first year and $17K per year after, and only 467 facilities a year the first three years would choose to implement the rule. After reviewing the requirements and discussing the proposed rule with other companies, it could be estimated that the rule will affect at least 1.2 million facilities within the US. Using EPA's own numbers, the cost effect to the economy is approximately 48 billion dollars. The $40,000 average is inaccurate, considering several companies have estimated that bringing their existing instruments into compliance to be over $100,000 per

instrument, not including the archiving costs. Several large companies have estimated the total cost of compliance for the proposed rule to reach 80-100 million dollars per company.

Recordkeeping – One Size Fits All

Since all electronic files are treated equally under the Proposed Rule, many items that are now kept electronically would be subject to the stringent requirements of subpart C, in the Proposed Rule. Low level risk e-records, such as master study schedules, SOPs, training records, etc, would all be forced into EPA compliance since they are required by Title 40. It was suggested by EPA, that we, the regulated community, offer suggestions as to how to discern between high level and low level risk e-records. We suggest that the Agency should look harder at the scope of the Proposed Rule and determine what the regulated community, who already use an abundance of e-records, could do to comply. Then the electronic recordkeeping rule can be crafted to allow for flexibility when accommodating high vs. low level risk e-records.

Records are also transferred when a business (or part of a business) is acquired from another company. Usually, different computer systems are used to keep similar data and records must be moved to the acquiring company. Often archived information is printed and only the paper copy is kept by the acquiring company. Sometimes data is manually or electronically transferred to existing electronic systems. Permission to access and use the systems at the divesting company is limited during the transition period and is stopped entirely once the transaction is completed. When two companies merge and both have central data systems, one is chosen and data from the other is transferred. Use of the second legacy system is then discontinued. The Proposed Rule would greatly increase the cost of acquisitions and divestitures if all legacy systems must be kept running for archive retrieval purposes.

Long Record Retention Periods

Because of the long recordkeeping requirements of some regulations, (e.g., Toxic Substances Control Act (TSCA) section 8(c) for 30 years and the Clean Air Act's Boilers and Industrial Furnaces' monitoring for life of the facility), maintaining the data electronically will be very burdensome given the short lifetimes of computer systems. Requirements for longterm access to electronic data means that data must be transferred from system to system each time it is changed unless archiving of printed copies is allowed.

In addition, the FIFRA program has a virtual indefinite period under which record retention is required. This indefinite time period will result in an increased risk that data from one system might not be completely formatted and migrated correctly into the new system, causing a breach in compliance. Since it is impossible to know what types of technologies will be available in the future, it becomes very challenging for a regulated entity to manage what will be very large caches of data and records from system to system for an indefinite time period. However, the rule could be amended to allow for the transition or migration of the records from an electronic medium to a different medium, possibly even paper, should an existing system become obsolete. The OECD draft guidance document on electronic records has such a statement, whereby records can be migrated to a different medium should their equipment or software become technologically obsolete.

Contract Laboratory Data

We are especially concerned about data generated at contract labs. There are a large number of contract laboratories involved in providing data used to support environmental regulations for sponsor companies. The data collection systems at the contract facility may not be compatible with any existing technology at the sponsor level and requires printing as the only viable option to transfer the original data back to the sponsor. Under the Proposed Rule, these migration issues would prohibit the data owner from taking possession of the original raw data.

Many States require laboratories to be accredited for certain programs, most frequently including the Safe Drinking Water Act, Clean Water Act and Resource Conservation and Recovery Act. Some States also have Clean Air Act accreditation requirements. In addition, many States have adopted the National Environmental Laboratory Accreditation Conference (NELAC) criteria for their accreditation programs. This program is a standard setting organization led by EPA with other federal agencies, States and contributors participation. In the extensive Quality Systems chapter of the standards, it states in 5.6.2 (Laboratory Management Responsibilities) paragraph h):

> "Developing a proactive program for prevention and detection of improper, unethical or illegal actions. Components of this program could include: internal proficiency testing (single and double blind); post-analysis, electronic data and magnetic tape audits; effective reward program to improve employee vigilance and co-monitoring; and separate SOPs identifying appropriate and inappropriate laboratory and instruments manipulation practices." [1]

This and similar requirements in the Good Laboratory Practices (GLPs) written in the EPA's TSCA and FIFRA regulations should suffice for systems management means of preventing fraud. EPA's electronic recordkeeping requirements should not impose additional requirements nor conflict with existing regulations/programs that have fraud prevention already incorporated.

EPA has not shown in the Proposed Rule that this type of system will prevent fraud or result in higher quality data. In most cases, installing an electronic system has improved efficiency, removed a source of transcription errors and in general made it harder to commit fraud since there is less human manipulations of the data.

Reporting

BASF has facilities in many States and reports to many agencies. If States decide on vastly different reporting formats, it would be a burden for us to try to satisfy all the differing report formats and transmission protocols. We would like EPA to only approve State programs which meet standard and similar criteria. Ideally, the criteria would be standardized at the federal level for all States to use.

The frequency of renewal of registration (p. 46181) should depend on the frequency that reporting is required. For example, it doesn't make sense to renew every 2 years when the TSCA Inventory Update Rule (IUR) report is due only every 4 years. We propose that the frequency should vary depending on the nature of the reporting. Monthly or quarterly reporting may be renewed every 2 years while annual or longer reporting intervals would be renewed every 4

[1] NELAC Chapter 5, Quality Systems, Revision 15, May 25, 2001.

years or longer. Often, different people are responsible for different reports, so that they would have separate registrations anyway.

Central Data Exchange (CDX)
The public key infrastructure (PKI) process is so cumbersome, especially for setting up the signature, that people will avoid it. In contrast, Food & Drug Administration's 21 CFR Part 11, section 11.50 - 11.200 requirements do not specify the technology to be used. EPA should follow suit and only include the requirements for signature, rather than limiting the technology to only the use of PKI. In the future, as the technology improves, more options will be available and we shouldn't be limited by what is currently feasible.

For a large company, we will need many digital certificates at each site as different people have different responsibilities. In fact, for the last TSCA IUR report, some sites had different people signing different pages of one site report. We are not aware of any provisions in this proposed rule to handle such a scenario other than to submit multiple reports from one site or continue submitting paper reports.

The CDX process is not technology neutral if only certain software can be used to access it. For example, the EPA's beta test for electronic TSCA Test Submissions (TSCATS) submittals specifies that a recent version of Microsoft Internet Explorer be used and that Netscape Navigator will not work. Also, on p. 46183 of the proposed rule, it specifies that Windows 95, 98 or NT 4.0 is needed. This year BASF will be switching to Windows 2000 and will not have any older operating systems available. As written, the Proposed Rule is not technology neutral and it's not even keeping up with current technology.

We appreciate the opportunity to provide comments on this Proposed Rule. If you have any question about these comments, please feel free to contact me at 734-324-6334.

Sincerely,

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